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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,150	09/27/2004	Sung-Jin Kim	AP036-04	5035

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EXAMINER	
CLARK, AMY LYNN	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/509,150	KIM, SUNG-JIN	
	Examiner	Art Unit	
	Amy L. Clark	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04/25/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 48-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-8 and 48-83* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group I, Claims 1-8 and 48-74 in the reply filed on 04/25/2006 is acknowledged. Acknowledgement is also made of Applicant's amendment submitted on 04/25/2006, wherein claims 1, 2, 50 and 55-74 are amended, claims 9-47 are cancelled and claims 75-83 are withdrawn. Due to the amendment of claims 55-74, a new election/restriction is required.

Currently, Claims 1-8 and 48-83 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-8 and 48-54, drawn to a composition for protecting brain cells or improving memory; said composition comprising an extract of Liriopsis tuber from about 50 to 500 mg; and at least one pharmaceutically acceptable carrier, said pharmaceutically acceptable carrier is talc from about 0.5 to 5.0 mg and lactose from about 50 to 500 mg.

Group II, claims 55-64, drawn to a composition for protecting brain cells or improving memory; said composition comprising an extract of Liriopsis tuber from about 50 to 500 mg; and at least one pharmaceutically acceptable carrier, said pharmaceutically acceptable carrier is starch from about 1.0 to 10 mg and magnesium stearate from about 10 to 100 mg.

Group III, claims 65-69, drawn to a composition for protecting brain cells or improving memory; said composition comprising an extract of Liriopsis tuber is about 20 g of isomerized sugar, 5.0 mg of antioxidant, 2.0 mg of methylparaoxybenzoate and about 100 ml of purified water.

Group IV, claims 70-74, drawn to a composition for protecting brain cells or improving memory; said composition comprising an extract of Liriopsis tuber from about 50 to 500 mg; and at least one pharmaceutically acceptable carrier, said pharmaceutically acceptable carrier is about 1.0 mg or antioxidant, 1.0 mg of Tween 80 and 2.0 ml of distilled water.

Group V, claim 75, drawn to a method for protecting brain cells against damage caused by excitatory amino acids and oxidative stress in a mammal comprising administering to said mammal a therapeutic amount of an extract of Liriopsis tuber of claim 3, wherein said extract of Liriopsis tuber is administered in an amount of from 0.1mg/kg to 500 mg/kg, and wherein said extract is administered to said mammal via a route selected from the group consisting of oral administration, topical application, sterile injection, inhalation, beverage, food product and rectal administration.

Group VI, claim 76, drawn to a method for inhibiting APMP-induced depolarization of a neuronal cell of a mammal comprising administering to said mammal therapeutic amount of an extract of Liriopsis tuber, wherein said extract of Liriopsis tuber is administered in an amount of from 0.1mg/kg to 500 mg/kg and wherein said extract is administered to said mammal via a route selected from the group consisting of oral administration, topical application, sterile injection, inhalation, beverage, food product and rectal administration.

Group VII, claims 77-79, drawn to a method for facilitating tyrosine phosphorylation of a hippocampal protein of a mammal.

Group VIII, claim 80, drawn to a method of inhibiting cholinesterase activity in the brain of a mammal.

Group IX, claim 81, drawn to a method of treating neurodegenerative diseases of a mammal.

Group X, claim 82, drawn to a method of preventing or treating dementia of a mammal comprising administering a medicament to a mammal.

Group XI, claim 83, drawn to a method of improving memory of a mammal comprising administering a medicament to said mammal.

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Claims 1 and 3, at least, are anticipated by or obvious over Kim (Japan Patent Abstract: JP 06107555 A; 04/1994). For instance, Claim 1 is drawn to a composition for protecting brain cells or improving memory, said composition comprising of an extract of Liriopsis tuber and a pharmaceutically carrier. Kim teaches a Chinese traditional medicine microcapsule for treating neurosis comprising of an extract of *Ophiopogon japonicus* (which is synonymous with Liriopsis) tuber and lactose. Kim further teaches that the extract of *Ophiopogon japonicus* tuber is obtained by extraction with aqueous ethanol. However, it should be noted that Claim 3 constitutes a Product-by-Process type claims. In Product-by-Process type claims, the process of producing the product is given no patentable weight since it does not impart novelty to a product when the product is taught by the prior art. See *In re Thorpe*, 227 USPQ 964 (CAFC 1985); *In re Marosi*, 218 USPQ 289, 292-293 (CAFC 1983) and *In re Brown*, 173 USPQ 685 (CCPA 1972). Consequently, even if a particular process used to prepare a product is novel and unobvious over the prior art, the product *per se*, even when limited to the particular process, is unpatentable over the same product taught in by the prior art. See *In re King*, 107 F.2d 618, 620, 43 USPQ 400, 402 (CCPA 1939); *In re Merz*, 97 F.2d 599, 601, 38 USPQ 143-145 (CCPA 1938); *In re Bergy*, 563 F.2d 1031, 1035, 195 USPQ 344, 348 (CCPA 1977) *vacated* 438 US 902 (1978); and *United States v. Ciba-Geigy Corp.*, 508 F. Supp. 1157, 1171, 211 USPQ 529, 543 (DNJ 1979). Finally, since the Patent Office does not have the facilities for examining and comparing Applicant's composition with the compositions of the prior art reference, the burden is upon Applicant to show a distinction between the material, structural and functional

characteristics of the claimed composition and the composition of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). Although Kim does not expressly teach lactose in an amount of 50 to 500 mg and Liriopsis tuber in an amount of about 50 to 500 mg, the composition as taught by Kim, has the same use as the composition claimed by Applicant, therefore the composition is one in the same as the composition claimed by Applicant and it would be merely a matter of judicious selection well within the purview of one of ordinary skill in the art to adjust the amounts of each ingredient. Consequently, the special technical feature which links the claims does not provide a contribution over the prior art, so unity of the invention is lacking.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Group I:

Specie A: elect at least one pharmaceutically acceptable carrier from Claim 1, Claim 2, Claim 51, Claim 52, Claim 53 or Claim 54.

Specie B: elect one method of extracting from Claim 3, Claim 4, Claim 5 or Claim 6.

If the method is chosen from Claim 3, further elect one solvent from Claim 3.

Specie C: elect one additive from Claim 7 or elect the additional ingredients from Claim 50.

If an additive is elected from Claim 7, then elect either a beverage from Claim 48 or a food product from Claim 49.

Group II:

Specie A: elect one pharmaceutically acceptable carrier from Claim 55

Specie B: elect one method of obtaining Liriopsis tuber from Claim 56, 57, 58 or 59.

If the method is chosen from Claim 56, further elect a solvent from Claim 56.

Group III:

Specie A: elect one pharmaceutically acceptable carrier from Claim 60.

Specie B: elect one method of obtaining Liriopsis tuber from Claim 61, 62, 63 or 64.

If the method is chosen from Claim 61, further elect a solvent from Claim 61.

Group IV:

Specie A: elect one pharmaceutically acceptable carrier from Claim 65.

Specie B: elect one method of obtaining Liriopsis tuber from Claim 66, Claim 67, Claim 68 or Claim 69.

If the method is chosen from Claim 66, further elect a solvent from Claim 66.

Group V:

Specie A: elect one pharmaceutically acceptable carrier from Claim 70.

Specie B: elect one method of obtaining Liriopsis tuber from Claim 71, Claim 72, Claim 73 or Claim 74.

If the method is chosen from Claim 71, further elect a solvent from Claim 7

Group VI:

Specie A: elect one route of administration from Claim 75.

Group VII:

Specie A: elect one route of administration from Claim 76.

Group VIII:

Specie A: elect one route of administration from Claim 77.

Specie B: elect one hippocampal protein from Claim 78 or Claim 79.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 75-80.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy L. Clark
AU 1655

Amy L. Clark
May 5, 2006

Michele C. Flood

MICHELE FLOOD
PRIMARY EXAMINER